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1 Attorney Docket No. 80157

2  
3 ACTIVE ACOUSTIC ARRAY FOR ULTRASONIC BIOMEDICAL APPLICATIONS  
4

5 STATEMENT OF GOVERNMENT INTEREST

6 The invention described herein may be manufactured and used  
7 by or for the Government of the United States of America for  
8 governmental purposes without the payment of any royalties  
9 thereon or therefor.  
10

11 CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

12 Not applicable.  
13

14 BACKGROUND OF THE INVENTION

15 (1) Field of the Invention

16 The present invention relates to a device having an  
17 acoustic array, which device has utility in ultrasonic  
18 biomedical applications, particularly in the detection of breast  
19 cancer.

20 (2) Description of the Prior Art

21 Current breast cancer screening techniques which rely on X-  
22 rays are painful to undergo and often ineffective for detecting  
23 early stages of cancer. Conventional ultrasound systems, i.e.,  
24 hand-held linear b-scan arrays, are limited by the maximum

allowable levels of exposure to the ultrasound set forth by the Food and Drug Administration (FDA).

Ultrasound technology has been used in the medical field for many applications ranging from monitoring the heart condition of individuals to monitoring fetal development. There are a number of patents which illustrate various features of ultrasound equipment used in medical applications. For example, U.S. Patent No. 5,042,492 to Dubut illustrates a probe used in ultrasound apparatus. The probe is formed with a concave attack face using a continuous acoustic transition blade. The blade is metallized and is in common contact with all the front metallizations of a series of piezoelectric elements of the probe. The rear metallizations of the elements terminate electrically and independently backwards of the probe. The probe has utility in ultrasound experiments where good focusing is desired.

U.S. Patent No. 5,122,993 to Hikita et al. relates to a piezoelectric transducer which converts electric signals into sound waves or other mechanical vibrations or converts mechanical vibrations into electric signals and which has utility in the transmission/reception of sound waves into/from the human body. The piezoelectric transducer has plural piezoelectric transducer elements which can generate mechanical vibrations converging substantially on one point. The

1 transducer is formed to control the convergent point by  
2 insulating piezoelectric transducer elements mechanically,  
3 arranging them concentrically and driving them independently and  
4 separately from each other.

5 U.S. Patent No. 5,680,863 to Hossack et al. relates to a  
6 phased array transducer for an ultrasonic imaging system. The  
7 transducer includes a flexible support element which supports an  
8 array of piezoelectric transducer elements. Shape transducers  
9 such as strain gauges or capacitive transducers are coupled to  
10 the support element to generate a signal indicative of the  
11 instantaneously prevailing curvature of the array. A user-  
12 controlled actuator is coupled to the support element to flex  
13 the support element between at least first and second  
14 configurations wherein the support element has separate  
15 curvatures along the axis of the transducer in each of the first  
16 and second configurations.

17 U.S. Patent No. 5,713,356 to Kruger relates to a  
18 photoacoustic breast scanner which uses incident electromagnetic  
19 waves to produce resultant acoustic waves. Multiple acoustic  
20 transducers are acoustically coupled to the surface of the  
21 tissue for measuring acoustic waves produced in the tissue when  
22 the tissue is exposed to a pulse of electromagnetic radiation.  
23 The multiple transducer signals are then combined to produce an

1 image of the absorptivity of the tissue, which image may be used  
2 for medical diagnostic purposes.

3 U.S. Patent No. 5,305,752 to Spivey et al. relates to an  
4 acoustic imaging device. The devices consist of a ring of  
5 acoustic transducers which encircle a medium to be imaged. The  
6 medium is sequentially insonified by each transducer with  
7 subsequent reception of the scattered waves by the remaining  
8 transducers. The device may be used for imaging human tissue in  
9 vivo and in vitro.

10 The current invention describes a stationary array  
11 amenable to repetitive averaging of the ultrasonic field at  
12 lower intensity for longer periods.

13

#### 14 SUMMARY OF THE INVENTION

15 Accordingly, it is an object of the present invention to  
16 provide a device which may be used to screen human tissue for  
17 cancerous tissue.

18 It is a further object of the present invention to provide  
19 a device as above which has particular utility in the detection  
20 of breast cancer.

21 The foregoing objects are attained by the device of the  
22 present invention.

23 In accordance with the present invention, a device for  
24 detecting cancer in human tissue is provided. The device

1 broadly comprises an acoustic array shaped to conform to and  
2 surround a portion of the human anatomy and means to  
3 acoustically couple the acoustic array to the portion of the  
4 human anatomy. The acoustic array is doubly curved having a  
5 first curvature along a first axis and a second curvature along  
6 a second axis perpendicular to said first axis.

#### 8 BRIEF DESCRIPTION OF THE DRAWINGS

9 Other details of the doubly curved inward radiating  
10 acoustic array device of the present invention, as well as other  
11 objects and advantages attendant thereto, are set forth in the  
12 following detailed description and the accompanying drawings  
13 wherein like reference numerals depict like elements, wherein:

14 FIG. 1 is a schematic representation of a device for  
15 detecting cancer in human tissue in accordance with the present  
16 invention;

17 FIG. 2 is a schematic representation of the segments  
18 forming the acoustic array used in the device of FIG. 1;

19 FIG. 3A is a sectional view of the acoustic array used in  
20 the device of FIG. 1 surrounding a human breast;

21 FIG. 3B is an enlarged view of a portion of the acoustic  
22 array;

1        FIG. 3C is a rear view of the acoustic array of FIG. 3A;  
2        FIG. 4A is a top view of a flat sheet of piezoelectric  
3 material from which the acoustic array segments are formed; and  
4        FIG. 4B is a sectional view of a flat sheet of  
5 piezoelectric material from which the acoustic array segments  
6 are formed.

7  
8                    DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

9        Referring now to FIGS. 1, 2, 3A - 3C, and 4A - 4B, the  
10 present invention relates to a device 10 having a doubly curved  
11 acoustic array 12 which surrounds a portion 14 of the human  
12 anatomy, such as a female breast. The acoustic array 12 is said  
13 to be doubly curved because it has a first curvature along a  
14 first axis and a second curvature along a second axis  
15 substantially perpendicular to the first axis. The device 10 is  
16 intended to screen for abnormal tissue using ultrasonic waves.

17        As can be seen from FIG. 2, the acoustic array 12 is  
18 preferably formed in segments 16. Each segment 16 is formed by  
19 a flat sheet 18 of piezoelectric material as discussed below.  
20 As shown in FIG. 4, the piezoelectric material has a plurality  
21 of rods 20 formed from the piezoelectric material, such as a 1 -  
22 3 piezocomposite material, extending between a first surface 22  
23 of the sheet 18 and a second surface 24 of the sheet 18. Each  
24 of the rods 20 is surrounded by a polymeric material 26 and thus

1 electrically and mechanically (or acoustically) insulated from  
2 adjacent rods 20. The rods 20 can have various cross sections,  
3 i.e., square, elliptical, etc.

4 A plurality of acoustic elements 28 are formed on the first  
5 surface 22 of the sheet by metallizing the surface 22 to form a  
6 specific pattern of acoustic elements 28 wherein the acoustic  
7 elements 28 may be randomly or regularly distributed over the  
8 array aperture. Any suitable metallizing technique known in the  
9 art, such as electroplating, can be used to form the specific  
10 pattern of acoustic elements 28. Preferably, each of the  
11 acoustic elements 28 is joined to, and thus electrically  
12 connected to, a first end of a plurality of rods 20. Each of  
13 the acoustic elements 28 functions as an acoustic transmitter  
14 and receiver.

15 A continuous electrode 30 is formed on the surface 24 of  
16 the sheet 18 by metallizing the surface 24 using any suitable  
17 technique known in the art, such as electroplating. Preferably,  
18 the continuous electrode 30 is formed from a copper based  
19 material. The continuous electrode 30 is formed so that it is  
20 in both physical and electrical contact with a second end of  
21 each of the rods 20 and acts as a common ground.

22 In a preferred embodiment of the present invention, the  
23 surface 22 comprises an outer surface of the sheet 18 and the  
24 surface 24 comprises an inner surface of the sheet 18.



1       As previously mentioned, the acoustic array 12 preferably  
2 has a first curvature along a first axis and a second curvature  
3 along a second axis. This is achieved by taking the flat sheet  
4 18 forming each segment 16 and developing a desired curvature to  
5 the sheet. This may be done using any suitable technique known  
6 in the art. Preferably, the profile of each segment 16 is  
7 obtained from the mercator projection of the curved surfaced  
8 onto a flat plane. A thermoplastic, back fill material 26  
9 surrounding the rods 20 is used to allow the segments 16 to be  
10 curved at an elevated temperature and then cooled to provide a  
11 particular parabolic geometry, such as that shown in FIGS. 1 and  
12 3. In the present invention, a parabolic geometry is used so  
13 that the acoustic array 12 formed by the segments 16 has a shape  
14 which conforms to and surrounds a portion 14 of the human  
15 anatomy, such as a female breast.

16       Electrical wires or cables 34 extend through the backing  
17 material 32. Each wire or cable 34 is connected to one of the  
18 acoustic elements 28 at one end and to a voltage source 36 at  
19 the opposite end. The voltage source 36 is used to excite one  
20 of the acoustic elements 28 at a time and thus cause an  
21 ultrasonic sound wave to be generated into the portion 14 of the  
22 human anatomy. As previously mentioned, each of the acoustic  
23 elements 28 acts as both a transmitter and a receiver. Thus,  
24 when one of the acoustic elements 28 is excited, the other

1 acoustic elements 28 act as receivers for detecting the  
2 reflected sound wave.

3 The acoustic array 12 is acoustically coupled to the  
4 portion 14 by a coupling material 38. The coupling material 38  
5 must be a suitably contained lossless fluid. This fluid should  
6 be a biocompatible, non-toxic material such as silicone or  
7 water.

8 The device 10 further has a housing 40. The acoustic array  
9 12 is positioned within the housing 40. The backing material 32  
10 serves to decouple the acoustic array 12 from the housing 40 and  
11 provides acoustic impedance for a wide spatial bandwidth. The  
12 backing material 32 may comprise any suitable acoustically  
13 absorptive material known in the art. The housing also contains  
14 signal conditioning electronics 42 and the voltage source 36.  
15 The signal conditioning electronics 42 receive electric signals  
16 received by the acoustic elements 28 and are connected to the  
17 acoustic elements 28 via the wires or cables 34. The signal  
18 conditioning electronics 42 may be used to filter the signals  
19 received from the acoustic elements 28 to eliminate unwanted  
20 noise and to perform such other signal conditioning techniques  
21 as may be needed.

22 The device 10 further includes a central processing unit 44  
23 and a display 46. The central processing unit 44 may comprise  
24 any suitable computer known in the art and may be programmed in

1 any desired language. The central processing unit 44 is in  
2 communication with the signal conditioning electronics 42 and  
3 receives signals therefrom. The central processing unit 44 then  
4 converts the signals into acoustic images of the human tissue  
5 under examination of selected volume in cross section. Multiple  
6 pitch-catch views are combined to form each desired cross  
7 sectional image. This effectively halves the acoustic path  
8 length required in typical pulse-echo scenarios. In addition,  
9 the stationarity of the acoustic array 12 allows for spatial  
10 over sampling and time averaging schemes to be employed which  
11 further relax the transmit ultrasonic power levels to within  
12 current dosage maximums. The central processing unit 44 may use  
13 any suitable technique known in the art to generate 3-  
14 dimensional images. The display 46 is used to display the  
15 images generated by the central processing unit 44.

16 The central processing unit 44 is also preferably used to  
17 control the order in which the acoustic elements 28 are excited  
18 and to apply a broadband signal to the acoustic elements 28.

19 In operation, a first one of the acoustic elements 28 is  
20 excited by sending a first signal to it from the voltage source  
21 36, such as an alternating voltage source, and placing an  
22 electric field (voltage) across the piezoelectric material  
23 forming an element within the sheet 18. The piezoelectric  
24 material in response to the electric field changes shape and

1 gets thicker or thinner based on the instantaneous alternating  
2 voltage. This creates an initial acoustic wave having a  
3 broadband frequency content which then enters the human tissue  
4 under examination. When the initial acoustic wave encounters a  
5 change in specific acoustic impedance, such as a tumor, part of  
6 the acoustic wave is reflected and the remainder is transmitted.  
7 The reflected and transmitted waves are then detected or  
8 received by the other acoustic elements 28. The receiver  
9 elements 28 then convey the received signal to the signal  
10 conditioning electronics 42. This process is repeated over and  
11 over so that each of the acoustic elements 28 in the array 12 is  
12 used as a transmitter. In this way, a user of the device 10 can  
13 obtain an accurate picture of any tumor(s) in the human tissue  
14 under examination as well as a determination of the size, shape,  
15 and location of such tumor(s).

16 The device 10 and the acoustic array 12 are ideal for  
17 making tomographic scans since the acoustic elements 28 are  
18 spatially fixed with respect to each other. The inherent  
19 measurement stability and repeatability provided by the acoustic  
20 array 12 allows physicians or medical technicians to establish a  
21 pre-cancer baseline image for a given patient for future  
22 reference.

23 Another advantage of the present invention is that the  
24 acoustic array 12 can be sized for variations in breast size.

1        While the present invention has been described in the  
2 context of detecting cancer in a human breast, it should be  
3 recognized that the device can be adapted to detect cancer in  
4 other portions of the human anatomy.

5        It is apparent that there has been provided herein a doubly  
6 curved inward radiating acoustic array for ultrasonic medical  
7 applications which fully satisfies the objects, means, and  
8 advantages set forth hereinbefore. While the present invention  
9 has been described in the context of specific embodiments  
10 thereof, other alternatives, modifications, and variations will  
11 become apparent to those skilled in the art having read the  
12 foregoing description. Accordingly, it is intended to embrace  
13 those alternatives, modifications, and variations.

1 Attorney Docket No. 80157

2  
3 ACTIVE ACOUSTIC ARRAY FOR ULTRASONIC BIOMEDICAL APPLICATIONS  
4

5 ABSTRACT OF THE DISCLOSURE

6 The present invention relates to a device for detecting  
7 cancer in human tissue. The device comprises an acoustic array  
8 shaped to conform to and surround a portion of the human anatomy  
9 and a material for acoustically coupling the acoustic array and  
10 the human anatomy portion. The acoustic array is formed from a  
11 plurality of doubly curved segments. Each segment is formed by  
12 a piezoelectric ceramic polymer composite material with an  
13 acoustic element pattern formed on one surface via the selective  
14 deposition of a conductive material. The acoustic element  
15 pattern contains a plurality of acoustic elements which act as  
16 both transmitters and receivers. The acoustic array further  
17 includes a backing material which provides a desired mechanical  
18 damping to each segment and defines the shape of the array. The  
19 device further includes a housing which includes signal  
20 conditioning electronics to condition signals received from the  
21 acoustic array. A central processing unit is provided to create  
22 cross sectional images of the human tissue under examination. A  
23 display unit is provided to display the cross sectional images.

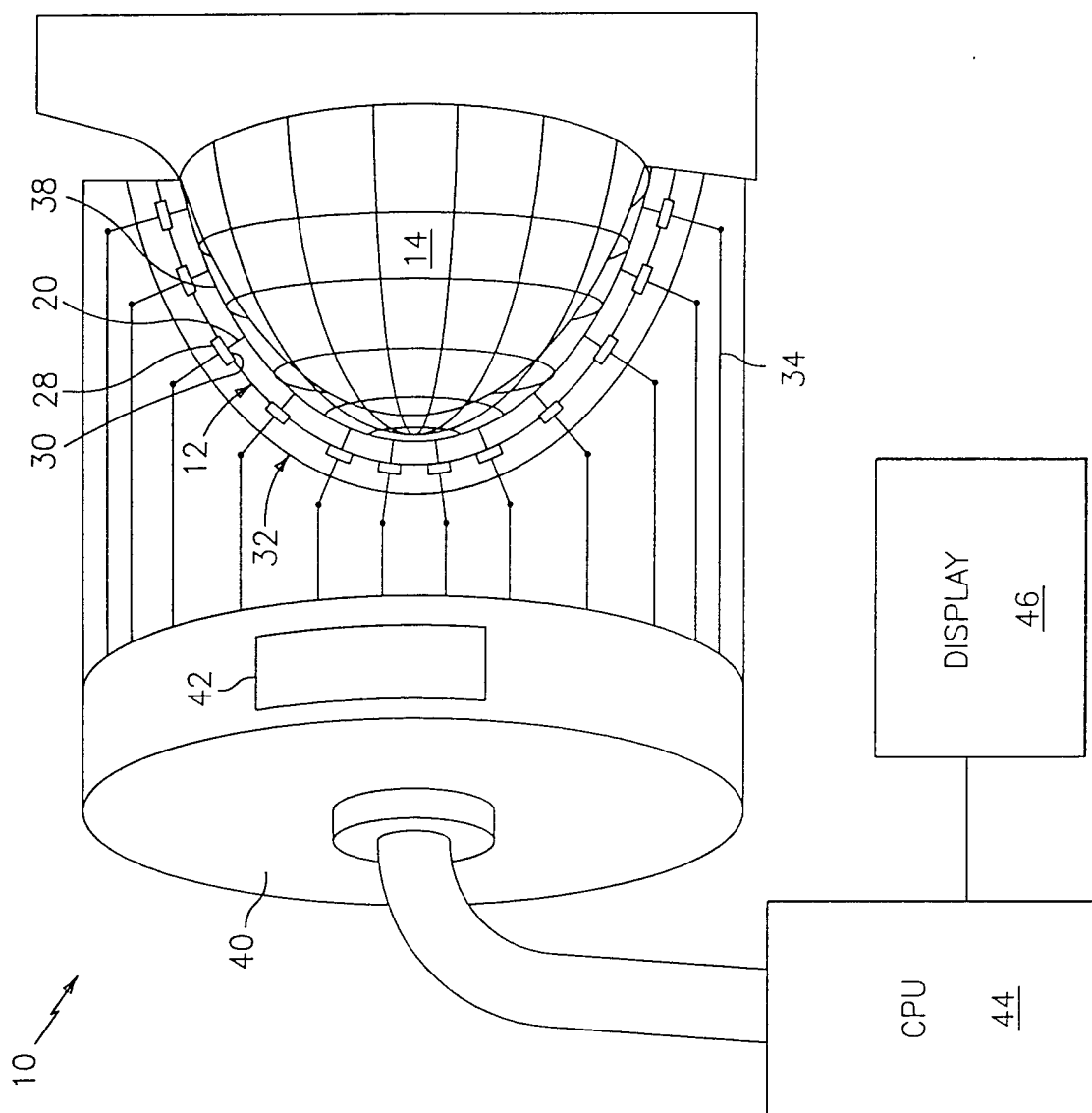
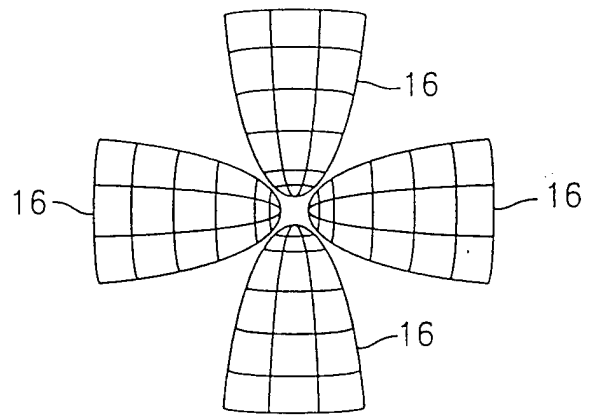
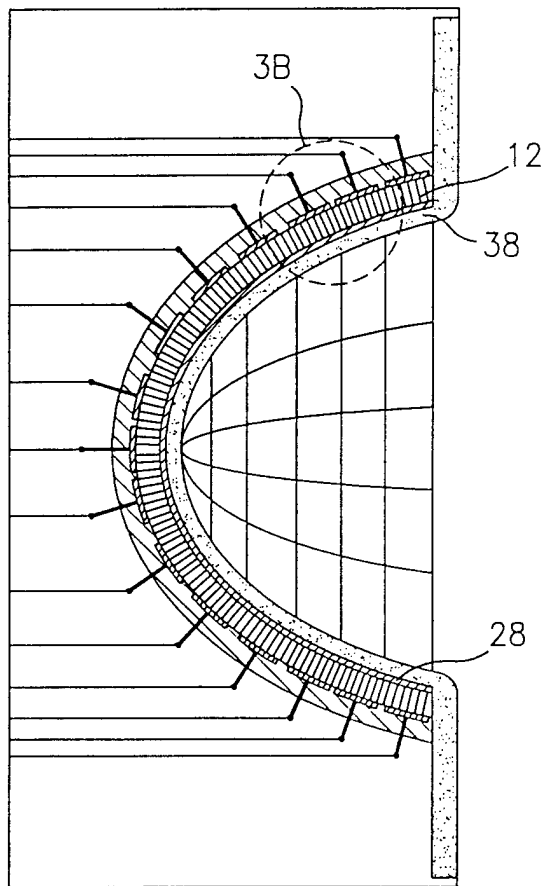
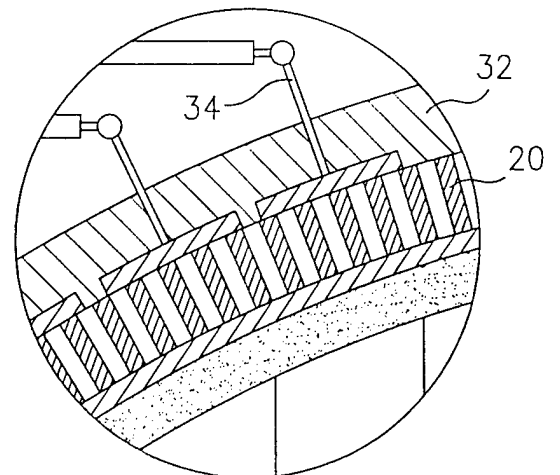


FIG. 1

*FIG. 2**FIG. 3A**FIG. 3B*



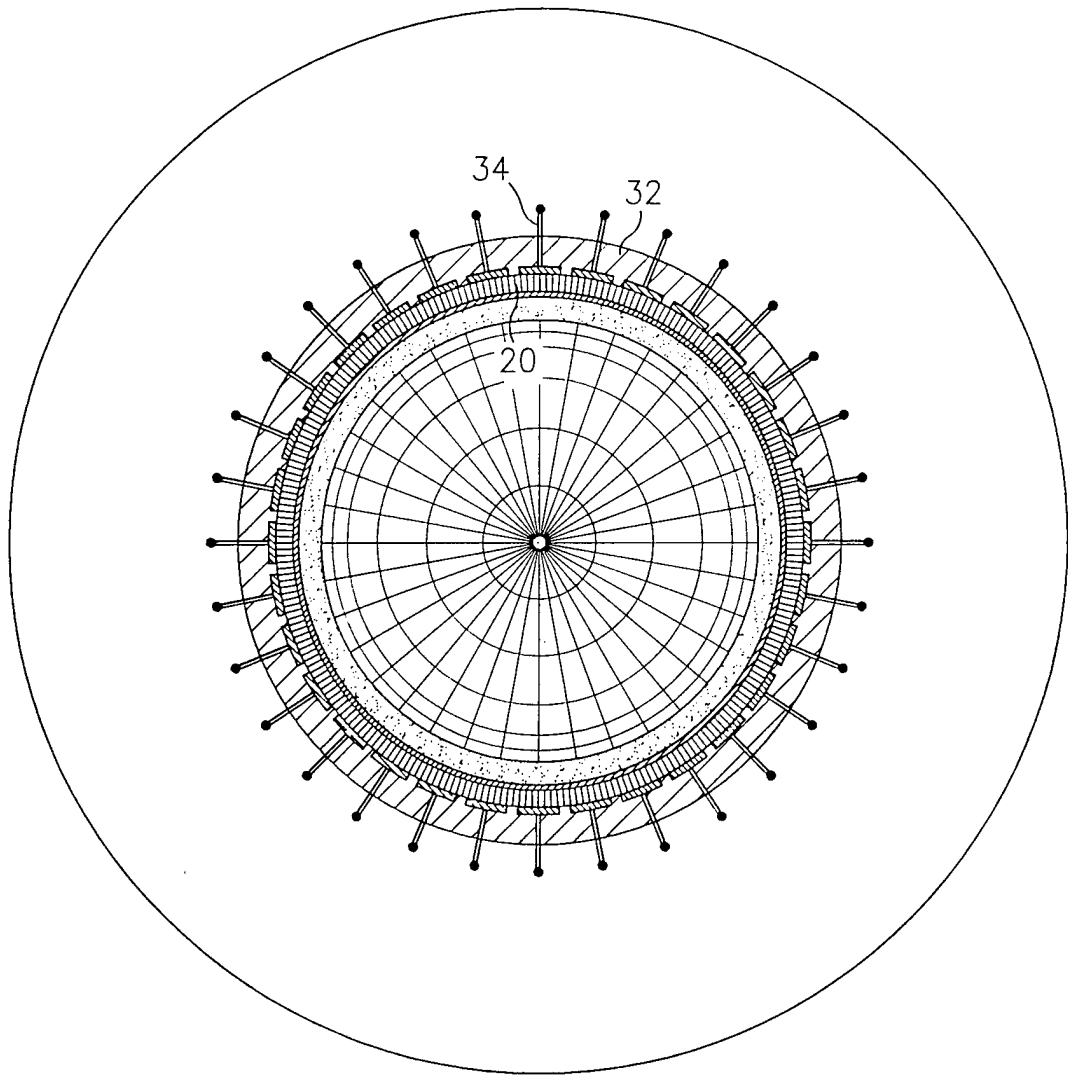


FIG. 3C

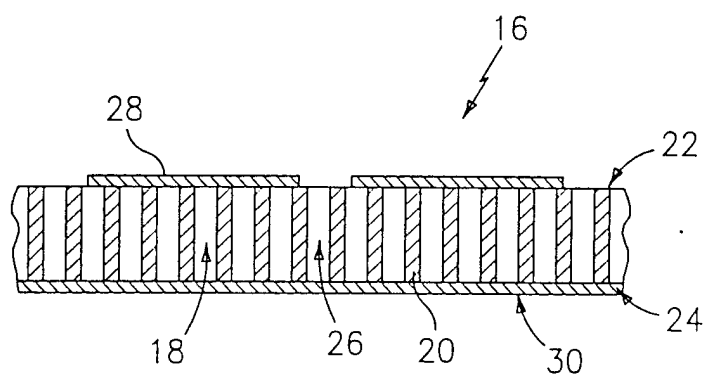


FIG. 4B

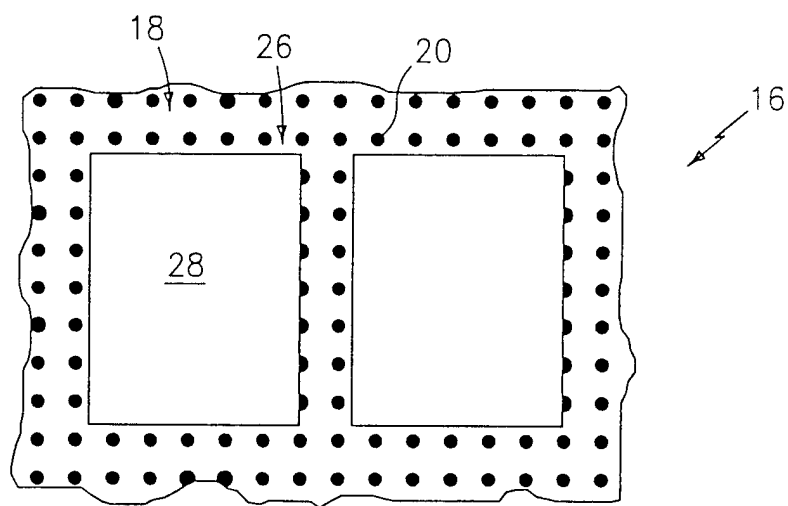


FIG. 4A